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Pharmaceutical Test Data Protection and Demands for Data-Exclusivity: Issues and Concerns of Developing Countries and India's Position

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Data-exclusivity is one of the most controversial issues in the current discussion on pharmaceutical intellectual property policy-making globally. It is aimed at protecting and safeguarding pharmaceutical test data submitted by pharmaceutical companies to drug regulatory authorities (DRA) for the purpose of obtaining marketing approval for new drugs. Most countries require the submission of test data relating to the efficacy and safety of pharmaceuticals and agro-chemicals as a condition for grant of marketing approval. Since the marketing approval process is laborious and expensive, the originators of such regulatory data demand protection for their investments through exclusivity periods, separate from any patent protection for the active ingredient. On the other hand, generic manufacturers advocate minimal protection for such data as they would be able to obtain speedier marketing approvals. Data-exclusivity thus, prevents during a set period of time, a second pharmaceutical applicant from obtaining a marketing authorization for its drug through a facilitated procedure; this procedure entails reliance by the second applicant on preclinical and clinical data generated by a pioneer company that prepared that data to support its own new drug application. The underlying logic of data-exclusivity suggests that it is an expression of trade-secrets, and that as such, data-exclusivity should be independent of patents. Compared with patents, the market power of data-exclusivity is, in theory, less restrictive, mainly because it does not legally prevent other companies from generating their own registration data. However, in practice, the vast financial resources and extended time required for gathering and generating pharmaceutical registration data for a new drug create a market barrier that is too high for generic based companies.

Keywords: TRIPS, Drugs and Cosmetics Act (DCA), 1940,Trans-Pacific Partnership (TPP) Agreement, European Union Data-exclusivity Union, 2005, data-exclusivity, drug regulatory authority, pharmaceutical patents, test data protection, research and development, new chemical entities

Developed countries pushed very hard during the TRIPS negotiations to have data-exclusivity included in the Trade Related Intellectual Property Rights (TRIPS) Agreement as a new kind of intellectual property right (IPR). They succeeded in part, as test data are mentioned in Section 7 of the TRIPS Agreement, but not entirely, as TRIPS does not talk about "exclusivity" as such. Data-exclusivity traces its concept to Article 39.3 of the TRIPS Agreement. There is no unanimity in the interpretation of Article 39.3. Presently, there are three emerging approaches to the interpretation of the provisions- the first that advocates data-exclusivity, the second that argues for data protection and the third that mandates a compensatory liability model.

Data-exclusivity is becoming an additional form of IP protection for research based pharmaceutical companies. Companies involved in research and development (R&D) spend a lot of time and money on the discovery of new products. It is well-known that a major share of research and development expenditure of pharmaceutical companies is spent on generation of pre-clinical and clinical trial data for approval of new drug. The research data or test data which is generated during R&D process of new drug is proprietary to innovator. The Data thus generated is submitted to drug regulatory authorities as a pre- requisite for marketing approval of the new chemical entities (NCE). This entire process may take about 12-13 years. Hence effective patent life comes about 7-8 years or even less.

Therefore, data protection systems, could if they provided exclusivity, become a partial substitute for patent protection, especially in countries which do not provide patent protection to pharmaceutical products or which are currently in the transitional periods of the TRIPS Agreement. This Article reflects upon pros and cons of the rationale for providing data-exclusivity towards new-drug development. It provides an in-depth analysis of the concept of data-

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exclusivity and its possible interfaces with regimes to regulate data-protection, patents and trade secret. It traces origin and definition of data-exclusivity by providing a detailed analysis of Article 39.3 of the TRIPS Agreement. It aims to analyse the arguments for and against data-exclusivity in an objective manner. It highlights the issues and concerns of developing and least-developed countries (LDCs), with a specific analysis of the India's position on the issue at hand. It elaborates ways towards ensuring public interest while granting Test-data Protection/Data-exclusivity. The article suggests a way forward for countries like India on the subject matter, and how best the obligations under Article 39.3 of the TRIPS are to be carried out by developing countries. Optimum period for the test data to be reasonably excluded for generic companies has also been deliberated upon. As it is well recognised, before a medicinal product can be used on patients, extensive tests are required so that the efficiency, safety, efficacy and quality of the product can be ascertained. Data-exclusivity is one of the most prominent regimes for test data protection – as it allows limited time duration during which only the generator of the trial data has the access to the data so as to ensure adequate return on investment. In certain cases, it is seen that 'data-exclusivity' helps originator companies to recover costs made on discovering and developing a new drug. Without data-exclusivity, the cost would take longer time period to be recouped. Long-time slack - from advancement to commercialization - may not be the situation with each medication or organization. India is considered to be the capital of generic medicines over the globe and it is argued that a strict data-exclusivity regime would jeopardize this status and availability of generic medicines to millions of poor in developing countries. Many authors argue that introduction of data-exclusivity in pharma field, would adversely affect at least partially, the hitherto proven capabilities of Indian generic industry.[1]

At present, India does not recognize data-exclusivity provisions. It is said that data-exclusivity provisions, if added to the Indian Drugs and Cosmetic Act, will prevent India's drug regulatory agency from referencing or otherwise relying on registration data previously innovator drug companies in order to gain regulatory approval for therapeutically equivalent generic versions.

This article seeks to proffer a platform to enable engagement, in-depth examination, and critical analysis of the overall feasibility (and hence, the eventual sustainability-quotient) of one of the key components underpinning the existing rules that impact and affect the development and disbursal of patented medicines, i.e., the somewhat contentious element of "data-exclusivity." Toward that end, we shall commence by contextualising data-exclusivity against the backdrop provided by the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights,[2] before moving on to outline its relationship with the conventional model of patent protection. Thereafter, we shall briefly review the possible costs and benefits of introducing data-exclusivity laws, in order to be able to appreciate the complex yet composite nature of the starkly heterogeneous global scenario, which prevails at present, and in the process, to hopefully arrive at a suitable model/proposition that countries would be well served to utilise; whilst negotiating bilateral trade agreements where such elements may well demand vital consideration.

New Drug Development

It is indeed a fact that the development of any new drug requires the undertaking of a very precisely detailed, meticulously phased and extensive testing process; first within heavily controlled laboratory conditions, thereafter on plants/animals/the environment (depending on the nature of the drug or chemical), and finally on human subjects; and the established norm per which these tests are conducted are, - at least in the later stages, - governed by rules set by the regulatory authorities, - designed to ensure the safety, quality, and efficacy of products being developed for the ultimate beneficial consumption by the concerned patient. There are economic, practical and ethical reasons why second/generic entrants into the pharmaceutical market should not attempt to reproduce the test data. The tests may take several years to complete and delay the entry of cheaper generics into the market; it will also generally be unethical to replicate tests on human subjects for products that have already demonstrated efficacy. The tests, particularly those involving human clinical trials, are relatively expensive and often require significant investments.

While innovations across many industry sectors are driving better returns and more efficiency at lower costs, this is not the case with pharmaceutical drug development. Studies on pharmaceutical industry data have suggested that the average total development

cost of a new drug is on the order of US$800 million, of which about 60% would be incurred in the conduct of trials (a substantial portion of these trials would be required for regulatory approval).[3] Because of the size of the required investment in clinical test data, the pharmaceutical industry argues that, the use of such data by third parties (other than the regulatory authority) must be prevented. If the regulator, relying on test data provided by the originator company at great expense, allows an equivalent product to enter the market, originator companies would have no incentive to incur the heavy costs necessary to bring new products to market in the first place. In practical terms, and in light of the prohibitive financial investment involved in replicating the originator product – an exclusivity rule that prevents use of the data by a third party (or the regulator relying on that data to approve a third party's generic product) has the simultaneous effect of deterring a potential competitor. This becomes exponentially more critical when applied to medicines, where, even if the cost were (arguably) not so very prohibitive, - there will additionally exist ethical concerns about repeating trials (that include an untreated control group) with a drug known to be efficacious.[4]

In India, as per the Drugs and Cosmetics Act (DCA), 1940 which concerns the market approval of drugs and Insecticides Act, 1968 which deals with chemicals, regulatory authorities have the obligation to insist for the submission of valuable data signifying the safety and efficacy for granting market approval for new drugs and chemicals. The basis for this provision is to ensure safety and quality of the product. As per the existing law, we have used a broad definition for new drugs for regulating approval of drugs. This includes new chemical entities, new combinations, dosages and indications. Test data of different types are insisted for providing approval of all these forms. However, the rules provide discretion to the authority to waive the data requirements in cases where the drug is already marketed in other parts of the world or there are sufficient published materials to show the safety of the drug. As per the Rule if the drug is already in the market in any other part of the world, only data of confirmatory clinical trials need be given for granting the approval to market it in India for the first time. The subsequent manufacturer of the same product in India need to give only bio-equivalence and bioavailability studies to get the approval. The full set of clinical trials, as per the rules, is mandated only in case where the drug substance is marketed in India for the first time in the world. Such cases as of now are limited but may increase in the context of the introduction of product patent protection for new drugs.

Conducting of confirmatory clinical trials and bio-equivalence/ bioavailability studies do not involve much effort. Based on these rules the Authorities now do not insist for clinical trial data for drugs already in the market in some part of the world. In such cases only data of confirmatory trials alone is insisted. In case of subsequent applicant seeking market approval for an approved new drug the data on bio-equivalence and bio-availability studies alone are insisted. Continuing this approach seems good for the Indian drug manufacturers particularly the generic industry. In 1988, major changes were introduced in the DCA to regulate the granting of approval of new drugs for manufacture or import.[5] Part X-A was added for the regulation of import of manufacture of new drugs including biological and special products. Rule 122-E gave a new and much wider definition of the term 'new drug'.[6] Irrespective of the fact that the safety and efficacy of a drug is established in another country, fresh data as to its safety must be submitted in India, but the level of clinical trials depends on the status of the drug in other countries.[7]

The matter, if not sufficiently unwieldy already, is visited with yet another layer of complexity, when one regards the position of developing countries that are either contemplating, or being obliged to contemplate some manner of a data-exclusivity regime.

Data-Exclusivity: Concept and Genesis

Data-exclusivity refers to a practice whereby, for a fixed period of time, drug regulatory authorities do not allow the registration files of an originator to be used to register a therapeutically equivalent generic version of that medicine. Data-exclusivity is an independent intellectual property right and should not be confused with the protection provided by other rights, especially patents. In fact, the strongest impact may be felt in a country where there is no patent for a medicine- if data-exclusivity is granted this will provide a monopoly for a set period. Data-exclusivity is one of the most controversial issues in the current discussion on pharmaceutical intellectual property policy making globally. It is aimed at protecting and safeguarding pharmaceutical registration files, i.e.

data submitted by pharmaceutical companies to drug regulatory authorities for the purpose of obtaining marketing approval for new drugs. The underlying logic of data-exclusivity suggests that it is an expression of trade secrets and that as such, data-exclusivity should be independent of patents. Compared with patents the, market power of data-exclusivity is, in theory, less restrictive, mainly because it does not legally prevent other companies from generating their own registration data. However, in practice, the vast financial resources and extended time required for gathering and generating pharmaceutical registration data for a new drug create a market barrier that is too high for generic-based companies.

Data-Exclusivity and Data-Protection

Data-exclusivity is a transitional concept of protection of exclusive test data in the form of publicly undisclosed information which is in between the protection of the data in the form of trade secrets based on the principles of equity and good faith and the domain of patent protection which requires invention to be new, having an inventive step and capable of industrial application. Thus while, every new invention is protected by patent, the need arises to evaluate the situation in developing countries where a generic drug manufacturer may develop drug at a cheaper price by proving its bioequivalence with the drug of an innovator company. It seems that the concept of data-exclusivity poses a conflict of interest between the innovator companies who have already availed of the protection under patent laws and public interest.

The exact definitions of data-exclusivity and data-protection are yet to be ascertained but looking at the world wide usage of the terms, certain aspects can be laid out for both of them. Analysing the European Commission's Report and Rules,[8] and WHO recommendations,[9]data-exclusivity can be said to be relating to the time frame for which the regulatory agency may be prevented from relying on originator's data to approve the products of potential generic competitors.[10] It does not create any new property rights but prevents unfair competition. It is mostly protection of clinical test trial data of a new compound but may also be used for new uses or indications of an already approved entity.[11]

In general terms, it refers to the protection of clinical test trial data of a new compound and its usage is mostly restricted to pharmaceutical and agro-chemical industry; but has the potential in wide array of subject matters. Whereas, data protection is a more generic term belonging to privacy laws, where individual's data is protected from unethical, unwarranted or unintended use. Hence, it won't be wrong to claim that data-exclusivity is a subset of data protection.

TRIPS Agreement: Article 39.3

The scope of protection of pharmaceutical test data has been a contentious issue due to the public policies and interests involved. Notwithstanding the long negotiating history behind the adoption of the TRIPS Agreements, Article 39.3 is a relevant example of how WTO Member States have not succeeded in overcoming their differences.[12] Nonetheless, WTO member states are aware that the TRIPS Agreement encompasses "*minimum international standard*" provisions, which constitute the bases for implementing TRIPS at national level.[13] Article 39.3 only applies if a member state imposes an obligation to submit data as a condition to obtain marketing approval of a drug, excluding those cases in which it is not necessary to submit such data, for instance, when the national authority relying on a prior registration given in another country grants marketing approval.[14] Before moving on to a more detailed discussion, - it bears noting at the very outset that, the present-day debate surrounding data-exclusivity largely derives from differing interpretations of the WTO TRIPS Agreement, on the subject. The relevant provision, Article 39(3) reads as follows:

"*Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use*."

Now while it is indeed true that there still persist somewhat un-reconciled views pertaining to the intended import of Article 39(3) of the WTO TRIPS Agreement, - it is handy to bear in mind that the overall provision, i.e., Article 39 broadly deals with the task of safeguarding trade secrets, against which

context, Article 39(3) enjoins member states with the following three obligations:

a) To protect data on new chemical entities, the collection of which involved considerable effort, against unfair commercial use[14]
b) To protect such data against disclosure, except where necessary to protect the public[14]
c) To protect such data against disclosure, unless steps are taken to ensure that the data is protected against unfair commercial use[14]

Now, while the first obligation is simply about protecting data submitted to regulatory agencies against unfair commercial use, the second and third obligations concern protecting data against disclosure to third parties, in the case of one or another exception. Although the generality of the wording does admittedly result in some lack of clarity about when disclosure would be justified by said exceptions (particularly in the third case),-the key point is that the obligation creates a presumption that the regulatory authority would not disclose data, without due reason, to a third party; The third obligation implies therefore, that disclosure is acceptable provided it can be ensured that disclosure will not lead to unfair commercial use, - and this is precisely where the proverbial plot thickens: multinational pharmaceutical companies have since been almost en masse, been in unequivocal favour of interpreting and using the term 'unfair commercial use' in a deliberately broad sense so as to mean and include data-exclusivity provision and are therefore demanding the enactment of the international data exclusivity laws, - in a concerted bid to justify and duly safeguard their investment of huge sums of money in to the protracted research and development processes of crucial drugs.

It thus follows that, a data-exclusivity regime, in sum, relates to how long the regulatory agency may be prevented from relying on originator's data to approve the products of potential generic competitors. Data-exclusivity does not relate to the question of disclosure to third parties and trade secrets dealt with in TRIPS Article 39(2) and (3), in which no time limits are specified.

Beyond the TRIPS Agreement

As a common practice, countries have entered into bilateral and multilateral treaties among themselves, where they have strengthened their IP regime beyond the TRIPS Agreement. One example for the same is Trans-Pacific Partnership (TPP) Agreement, which mandates the member countries to provide market exclusivity which prohibits third parties to rely on clinical data as submitted by the originators, in the absence of approval for a period of eight years or for a period of five years in addition to three years of market access barrier. Another example is the European Union Data-exclusivity Union 2005, which requires protecting clinical data through data-exclusivity for a period of eleven years, which includes eight years of data-exclusivity, two years of market exclusivity, which can be extended by one year.

The US's Hatch-Waxman Act (formally Drug Price Competition and Patent Term Restoration *Act* of 1984, Public Law 98-417) provides for data-exclusivity protection for a period of five years, and in the case of biologics, for a period of twelve years. The Article 1711 of the NAFTA Agreement also provides for the protection of clinical data, where the origination of such data involves considerable effort, except where the disclosure is deemed essential to protect the public or steps are taken to ensure protection of data from unfair commercial use. The reasonable period of protection is not less than five years. Treaty of Group of Three (Colombia, Mexico and Venezuela) also provides for similar protection period for commercialization of agro-components which use new chemical products.

Data-Exclusivity and Patents

With regard to a few salient points which very interestingly qualify the inter-relationship between data-exclusivity and the patent regime, it bears noting that, - once the patent period expires, or in an alternative scenario where a product is not covered by patent protection, - data-exclusivity does come into its own, as it were, - acting independently to delay the entry of any generic companies wishing to enter the market until the period of data-exclusivity is over; It may be noted though, that in most cases, the period of data-exclusivity may have no material effect if it is within the patent period, because exclusivity is protected by the patent.

The data-exclusivity right is a much stronger right than a patent because, unlike patent law, there are no exceptions or flexibilities that allow governments to tailor the law to national circumstances; for example: there is no ability for governments to provide the equivalent of a compulsory license, or data-exclusivity may act as a barrier to compulsory

licensing of a patent on the same product by preventing marketing authorization for a compulsory licensee. Data-exclusivity is attractive to originator companies because unlike a patent, data-exclusivity is automatic (rather like copyright). No fees are incurred for application or maintenance of the right, and there is more limited scope than exists in patent law for legal challenges, which are expensive to mount and to defend. It is for these reasons, that pharmaceutical companies are, almost without exception, strong proponents of data-exclusivity regimes.

Data-Exclusivity and Trade Secret

Many theories approach data-exclusivity with the same yardstick as trade secret and the idea itself stems from Article 39 of TRIPS Agreement.

a) In the course of ensuring effective protection against unfair competition as provided in Article 10bis of the Paris Convention (1967), Members shall protect undisclosed information in accordance with Paragraph 2 and data submitted to governments or governmental agencies in accordance with Paragraph 3.
b) Natural and legal persons shall have the possibility of preventing information lawfully within their control from being disclosed to, acquired by, or used by others without their consent in a manner contrary to honest commercial practices1 so long as such information: (a) is secret in the sense that it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question; (b) has commercial value because it is secret; and (c) has been subject to reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret.
c) Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use. [15]

The provision talks about the obligation of protecting the data between both private parties and in relation to government authorities to which such information must be submitted. The first Paragraph of Article 39 describes the structure of the provision: undisclosed information in general is protected as defined in Paragraph 2 and data submitted to governmental authorities and agencies are protected as defined in Paragraph 3.[16]

In common parlance, trade secret means 'self-generated information of commercial value kept secret'. It could comprise consumer profiles, list of customers and suppliers or may consist of information on distribution networks, advertising strategies or may include information on manufacturing processes and technical know-how.[17]

Unlike copyrights, patents, designs and layout circuit designs, trade secret cannot be claimed as a property rights.[18] The trade secret regime allows independent discovery/reverse engineering and its use by a third party. According to TRIPS, there are three criteria to be fulfilled to ascertain something as trade secret:

a) It must not be generally known or readily accessible by people who normally deal with such type of information.
b) It must have commercial value as a secret.
c) The lawful owner must take reasonable steps to keep it secret.

The footnote to Article 39.2 of TRIPS goes on to further elucidate that legal remedies should be available to address breach of contract, breach of confidence and inducement to breach, and acquisition of undisclosed information by third parties who knew or were grossly negligent in failing to know that acquisition was not based on honest commercial practices.

Now bringing the discussion to Indian scenario, we see that no legislation has been enacted explicitly guiding either data-exclusivity or trade secret regime. Therefore, in case of dispute, the claimant of trade secret generally tries to find recourse through a breach of contract, a violation of a confidence, torts or intellectual property.

One of the important criteria that the court has set with regard to claim of trade secret is that the owner must have made efforts to keep it a secret. The "quality of confidence" highlights trade secrets to be a legal concept.[19] With sufficient effort or through illegal acts rivals may access trade secrets

(confidential information). However, if the 'trade secret' or information owner proves that reasonable efforts were made to keep the information confidential, it (the information) remains a 'trade secret' and is legally protected. If, on the other hand, 'trade secret' owners cannot establish reasonable efforts to protect confidential information, they risk losing the quality of confidentiality of the information even if its information is obtained by rivals without permission.[20] A common knowledge, an information available in public domain or which can be inferred through some easily available information cannot be successfully claimed as trade secret. Hence, efforts made in maintaining confidentiality of an information is an important aspect that the Indian courts look at.[21]

But in common business parlance it is also, pertinent to share the information with certain persons like employees, partners, investors etc. for running the business, question raise that how to burden them with the obligation to maintain the confidentiality. Generally, in such kind of business setup, non-competition clause or confidentiality clause takes care of the matter. The employers put kind of negative covenants in the contract to restrain the other person from divulging the secret.[22] So, it is only through bounding the other person by some contractual clause that confidentiality could be maintained. Comparing the scenario with that of data-exclusivity, the other person in this case is a governmental authority to whom the claimant has provided the data for approval. Now the important question that lies before us is whether, in absence of any legislation or contractual obligation (reference to trade secret), the governmental authority is bound to protect that data.

At this point, the statement of Lord Greene in Saltman's Case must be referred. Lord Greene while deliberating on the remedies that should be available when confidential information is at stake explained three scenarios in this context, he had submitted that if there is a contract and a party receives confidential information, then even if the contract is silent on it, there would be an obligation on the receiving party to keep the information confidential. In another situation when a defendant has used confidential information obtained directly or indirectly from a plaintiff without the consent, express or implied, he would be guilty of infringement of the plaintiff's rights. In yet another situation, so long as the information was confidential, there would be obligations on the party receiving it whether or not there was an underlying contract.[23] Therefore, principles of equity do not consider any contract for the obligation of confidentiality to be put on the other party receiving the information.

One important observation from the above mentioned Lord Greene's three scenarios is that the receiving party's own understanding of the nature of information shared with him, in the absence of any contractual clause or instruction. The trade secret jurisprudence has laid down certain points to ascertain the nature of the information in the absence of any guidelines but in the context of data-exclusivity, the data available with the authority is of different nature and different consideration. Therefore, whether the principles of equity can also be applied in the claim of data-exclusivity is a question yet to be answered.

In the light of above discussion, it can be said that though data-exclusivity cannot be claimed as an intellectual property nonetheless some kind of exclusive rights can be claimed upon it. Though the jurisprudence on this subject matter is still in nascent stage but trait of information claimed under data-exclusivity is somewhere a mix of trade secret and data protection.

Arguments for and against Data-Exclusivity

There are two primary positions in the ongoing discussions about Article 39.3. The contrasting positions and interpretations of Article 39.3 have been well documented to date, and from this documentation, it is evident that these prominent interpretations are polarized. One side of the debate is led by the United States, the European Union and the multinational pharmaceutical industry, which interpret Article 39.3 as requiring a standard of "data-exclusivity" that includes preventing regulatory bodies of member states from relying on data submitted by the originator company when deciding whether to register a generic version of the same product. Many times, it is interpreted or it is forced upon developing countries that TRIPS Article 39.3 is talking about data-exclusivity, despite the fact that it has not mentioned about exclusivity anywhere, and it has not given any term for data-exclusivity. That's why there is a debate whether TRIPS Agreement is talking about data-exclusivity or data protection. It basically talks about two-fold protection, protection against unfair commercial use and protection against disclosure. When it's talking about the data it talks about data which companies have to generate to establish the quality, safety and efficacy of the drug

doing pre-clinical and clinical trials and other laboratory analysis.

Now the question is that in a Pharma value chain how do you finally receive a pill? There is a discovery of a molecule in case of the innovator product and after establishing that it is worth considering for clinical development it goes to the development phase and after finishing all the clinical trials, it is filed for the approval and then it goes for marketing after receiving the approval. But not all the products are innovator products. There are products which are either the exact copies of innovator products or they come from the incremental innovations. So, there are those generics or in licensed products which also reach the market. There is a clinical development component in both the cases. But in case of new drug there will be more phases. Generic drug is an identical or bioequivalent to a brand name drug. So there is no difference between an originator and a generic drug. The only difference is that the originators product is given a brand name because it was an innovative product of that company and generic company comes up with a replica of the originator. But as to the safety, strength, quality, efficacy there is no difference. In fact, there should not be any difference then only it's called a generic drug.

These generic drugs are substantially cheaper. So anything which comes at a less price can be bought more and can cover larger number of people. So, especially in larger programmers like TB, Malaria, HIV there is a need for a larger number of drugs which cannot be met by branded drugs. Even generic companies have to do some clinical trials in order to establish the safety and efficacy of the drug. Phase III and Phase III a, b are there as a requirement for even generic products. So when a company comes with a generic filing, it has to do clinical trials, it has to establish some physical data. So, it cannot be said that only innovator companies are going through this hard process of clinical trials. Now, if generic is equivalent, safe, high quality, then why there is this huge debate and why there is a need for data-exclusivity?

The issue here is that in those cases where the patent is no more or is not granted or patent has limited period for 20 years but it starts from the point when it's applied and the development of product takes some 13, 14 or 15 years. So actual economic effected period for patent may be 5 to 4 years but data-exclusivity as in most of the cases is 5 years or 6 years. It starts from the date when application is given approval for marketing. So it adds as a second layer of protection and that's why it's called a TRIPS-plus provision. So no matter you have an innovation, no matter its non-obvious, the innovator companies have second layer of protection in terms of data-exclusivity. And that's enough to block the competition from generic companies. Now think of a situation when there is no patent. If there is no patent then no generic can be launched because you have for the 5 years a second protection that does not allow the drug regulators to refer to the originators file for safety data because it is bound by the exclusivity.

Suppose a product was launched on the 14th year of its patent life. Therefore, it had only 5 years for effective patent life in terms of economic terms and on 20th year, the patent expires. However, if data-exclusivity is there it will continue for next one more year. Another issue is that why developing countries like China or many other countries have adopted data-exclusivity provision when it is not a requirement under TRIPS? The reason is that because it is TRIPS-plus, it is forced on countries to adopt data-exclusivity. This is where FTA comes. There are many clauses in FTA which are not TRIPS requirement but above that it is called TRIPS-plus. The most important reason why China adopted data-exclusivity is that it was not initially WTO member. And China in order to get that status started data-exclusivity.

Indian position is very clear. India does not accord any legal recognition to data-exclusivity. The Satwant Reddy Committee, which was formed to look into the matter whether India should go for data-exclusivity or not, clearly rejects the option of adopting a TRIPS-plus data-exclusivity regime and instead proposed an alternative model with transition arrangements. With industry groups and some developed countries, for example, the United States and the European Union having argued that Article 39(3) requires countries to create a regime of data-exclusivity by way of devising a form of time-limited intellectual property right, -the contentions/justifications of the proponents of said regime may be summed up as follows:

a) The test data which is submitted to the drug regulatory authorities to assess the quality, efficacy and safety of the drugs are a result of huge and risky investment made by the innovator companies, - both in terms of the time and the

moneys invested, - and any stance to dilute the force of the same would arguably be anti-competitive in the sense that it would directly deprive the innovator companies of their legitimate and reasonable profits by allowing the generic companies to avoid incurring expenditure on investments when launching the generic versions of patented drugs;[24]

b) In light of the fact that patent protection is not available in all countries in equal measure,-data-exclusivity laws at national levels are expected to encourage and act as an incentive for the innovator companies to launch innovative drugs even in those markets where adequate intellectual property protections may not available,[24] e.g., instances where new uses of the existing products have been discovered, or where the new products in the market have been deemed to be lacking in terms of meeting the necessary threshold for patent ability, and so on and so forth;

c) It has further been asserted that, multi-national pharmaceutical giants are of the view that without a national data-exclusivity law in place, developing countries could very well stand to lose out on foreign direct investment in the pharmaceutical sector as protection of test-data was crucial to a company's decision as to the final selection of location for clinical trials.[24]

A good example of the above ethos would be the stance maintained among others, by the United States in particular, which has sought, in post-TRIPS negotiations, to insert the language of NAFTA on data-exclusivity, or even stronger provisions, in negotiating bilateral free-trade agreements with developing countries. Countries that have reached such agreements include Bahrain, Jordan, Morocco, Chile, the Dominican Republic, and the countries of Central America.[25] It is thus, easily appreciable as to why there continues to exist equally cogent arguments in support of the validity of moving to institute a stringent data-exclusivity regime with specific regard to the pharmaceutical R&D sector, - as much as the contrary view.

Issues and Concerns of Developing and Least-Developed Countries (LDCs)

On the other hand, Developing countries including India interpret Article 39.3 to provide certain minimum standards concerning 'non-disclosure' obligations, usually termed 'data protection' as opposed to 'data-exclusivity'. This non-disclosure obligation allows for a 'permissive reliance' standard, leaving it open to national regulators to rely on test and other data submitted to them by originators for marketing approval of subsequent applicants.[26] Developing countries contend that a reasonable interpretation of "unfair commercial use" does not require the recognition of exclusivity rights, hence Article 39.3, has "left a wide room for manoeuvre for member countries to determine the appropriate means of protection.[26] The position of developing countries was explained in the United Nations Conference on Trade and Development (UNCTAD) in 1996, in the following terms:

"*The protection is to be granted against 'unfair commercial use' of confidential data. This means that a third party could be prevented from using the results of tests undertaken by another company as background for an independent submission for marketing approval, if the data had been acquired through dishonest commercial practices. However, Article 39.3 does permit a national competent authority to rely on data in its possession to asses a second and further applications, relating to the same drug, since this would not imply unfair commercial use*."[27]

So, there has been intense debate on whether it implies data-exclusivity or data protection. Developed countries have adopted data-exclusivity during which period the regulatory authority is barred from relying on any data submitted by the originator for approval of subsequent applications of the products. Developing countries including India adopted 'non disclosure' obligations, usually termed 'data protection' as opposed to 'data-exclusivity'. This 'non disclosure' obligation allows for a 'permissive reliance' standard, leaving it open to national regulators to rely on test and other data submitted to them by originators for marketing approval of subsequent applicants.

It was noticed that there was enough flexibility in the provisions of TRIPS Agreement for a country to determine appropriate means of protecting test data. In terms of Paragraph 4 of the Doha Declaration, the provisions are to be "interpreted and implemented in a manner supported of WTO members' right to protect public health and, in particular, to promote access to medicines for all. Hence, the approach to be adopted should use the flexibilities in TRIPS Agreement, keeping in view the national interest of the country.

It was realized that data requirements for registration of agro-chemicals differ considerably from those for pharmaceuticals. Several countries have accepted the difference and have made different provisions for regulating the protection of safety and efficacy data for the two sectors. Similarly, due to wide differences between pharmaceuticals and traditional medicines, there is a need to consider separate dispensation for them as well.

In sum, Article 39.3 clearly requires some form of protection for test data, but does not require member states to grant exclusive rights. Its main purpose is not to prevent the use of such data by governments, but to prevent unfair use by competitors. The correct interpretation that must be given to Article 39 is quite clear and unambiguous at this point. TRIPS does not make granting of data-exclusivity rights mandatory, but gives the member states the freedom to choose the nature and extent of protection they want to offer. The question as to whether or not a country should actually grant this right to pharmaceutical companies is a totally separate one, and that answer must be arrived on its own merits is not linked to the interpretation of Article 39 of TRIPS.[28]

Thus, focussing on the entirety of the debate surrounding Article 39(3), - it becomes fairly evident that it has largely concentrated on textual interpretation and how to "balance" the investments by innovator companies against the interests of generic pharmaceutical manufacturers and public health. Given the ambiguity regarding what the minimum requirements of Article 39(3) are, - various commentators have offered an alternative reading of the text, and have proposed that data-exclusivity is not required by Article 39(3) but that compensatory liability is.

While this "alternative" textual interpretation may not be absolutely accurate, - it is nevertheless being increasingly viewed as a possible way to appease those member states that have traditionally been demanding a strict data-exclusivity regime. In practice however, the interpretive status-quo is not necessarily as water-tight at all times as one would hope for: India for instance, had adopted the position that Article 39(3) did not in fact, require that pharmaceutical test data be granted exclusivity for any period of time. However, subsequent bilateral and free trade agreements between the United States and developing countries have impressed a reading of Article 39(3) requiring data-exclusivity.[28]

An Inter-Ministerial Committee, set up in 2004 to decide on how to implement Article 39(3) of TRIPS, had tabled a number of proposals and recommendations, including the payment of a royalty to the originator of the data. These were succeeded by the several other exercises, such as, the Mashelkar Report, the Satwant Reddy Committee Report, etc. However, many of the proposals and recommendations have since run into rough weather as it has been alleged by several quarters that they appear to have been envisioned in the abstract, without having examined in-depth, the practical implications on the market, and hence their long-term viability, both as an immediate economic tool, as well as a potential point for legislative bargaining / diplomatic leverage.[28] The Table 1 lists some data-exclusivity provisions across the globe.[29]

Table 1 — Data-exclusivity provisions across the globe

Region			Time duration
	United States of America		
Argentina	Law on the Confidentiality of Information and Products – Article 4 and 5	Also made for protection against dishonest commercial use of the information which is submitted to the local health authority to approve new chemical entities.	Not specified
Bolivia	Andean Community Decision 436 (2006)- Article 266	Exceptions for protection –Necessity to protect the public or steps are taken to ensure that data is protected against unfair commercial use.	Not specified
Brazil	Law 9.279 on Industrial Property , Title V- Crimes against Industrial Property , Chapter 6 – Protection against unfair competition- Article 195	A crime of unfair competition is committed by someone who divulges, exploits or uses, in the absence of authorization, the result of tests or other undisclosed data the elaboration of which involved considerable effort and which has been presented to government entities as a condition for approving the commercialization of products.	Not specified
Canada	Food and Drugs Regulations, Section C.08.004.1	After the day on which the first notice of compliance was issued to the innovator in respect of the innovative drug.	8 years

(*Contd*.)

Table 1 — Data-exclusivity provisions across the globe (*Contd.*)

Region			Time duration
Colombia	Data Protection Decree no.2085 Andean Community Decision 436 (2006)-Article 266	Three years counted from the market approval for the applications presented during the first year of the decree in force Four years counted from the market approval for the applications presented during the second year of the decree in force.	5 years
Mexico	Industrial Property Law (Article 86bis) Article 1711 NAFTA(Trade secrets)	Except where the disclosure is deemed essential to protect the public or steps are taken to ensure protection of data from unfair commercial use. The reasonable period of protection is not less than five years.	5 years
United States	Federal Food, Drug or Cosmetic Act , Section 505 (21.USC.355)(C)(3)(F) Public Health Service Act , Section 351 US freedom of Information Act (Section 552 (b)(4) of title 5)	The standard used to determine misappropriation of undisclosed information in the United States, is whether the information has been appropriated through inappropriate means. A trade secret which is private or confidential is an exception from requirements of disclosure.	5 or 12 years
		Europe	
European Union and European Economic Area	Article 13(4) Regulation (EEC) Article 14.11 of Regulation 726 /2004 and Article 10.1 and 10.5 of Directive 2001/83	Eight years of data-exclusivity with two years of marketing, which can be further extended by one year, provided that during the first eight years of the ten years , the innovator has obtained authorization for one or more therapeutic indication.	10 years
Switzerland	Decree on Medications- Section 3, Article 17	Application for approval of a medicine that is essentially same as an already approved medicine. In case of a new indication, time is three years.	10 years
Turkey	Regulations on licensing the Human Medical Products – Article 9 – Abbreviated license	Limited to the patent period of the molecule in Turkey	6 years
Ukraine	The law of Ukraine- On Amending Article 9 of the of the Law of Ukraine “on medicines”	Protection from disclosure and prevention from commercial use in bad faith.	5 years
		Africa/ Middle East	
Egypt	Intellectual property Law no. 82 (Article 55-62)	Undisclosed information is protected to information which results from significant efforts and which is presented to the concerned authorities on being requested to permit the marketing of the pharmaceutical chemical or agricultural products which use new chemical entities necessary for needed examinations for its marketing.	5 years
Iraq	Coalition Provisional Authority Order no. 81, “Patent, Industrial Design, Undisclosed Information, Integrated Circuits and Plant Variety Law.”	The protection of data from disclosure with the exception to the following a) Protection of public b) Precautions to guarantee unclassified commercial use of data.	5 years
Bahrain	Law no.(7) of the Year 2003 on trade secrets	Disclosure of information is prohibited in the following cases – a) when the information is confidential; b) it is of commercial value to the confidentiality; c) if the confidentiality was dependable on the effective measures undertaken by its legal holder to preserve it.	5 years
Jordon	Article(8) Trade Secrets and Unfair Competition Law no.15(2000)	Protection of data except in the following cases – a) protection of public b) where the competent authority has taken necessary steps to ensure that the data is protected against unfair commercial use.	5 years

(*Contd.*)

Table 1 — Data-exclusivity provisions across the globe (*Contd.*)

Region			Time duration
Morocco	Article 15.10: Measures related to a certain regulated products	Five years for pharmaceutical products Ten years for agricultural chemical products	5 years
Saudi Arabia	Decision no. 3218 : Regulations for the protection of confidential commercial information , later amended by decision no. 4315 of 2005	Should be a result of substantial efforts, as a precondition for approving the marketing of products or chemical agricultural products in which new chemical substances have been used.	5 years
United Arab Emirates	Decree No. 404/2000	Period for protection of data secrecy shall be period of validity of the patent over the original drug in the country of origin.	Not Specified
		Asia/Pacific Rim	
Vietnam	Intellectual Property Law, Article 128	Should involve considerable effort and expenses. Protection from unfair commercial usage and disclosure Exception- Protection of public	5 years
Taiwan	Pharmaceuticals Affairs Law, Article 40	Data-exclusivity for new indication with international data is immediate. 3 years (for those with international data) and 5 years (for those with domestic clinical trials)	5 years
Singapore	Medicines Act (Chapter 176)	The licensing authority may not, for a period of 5 years from the date of such grant, grant a product licence to another person in respect of that or a similar medicinal product on the basis of the grant of the earlier licence unless the holder of the earlier licence has given his consent to the grant on that basis.	5 years
Korea	Pharmaceuticals Affairs Law	New drugs, ethical drugs from already licensed drugs to be re-examined in 6 years and ethical drugs which are identical to the already licensed drugs and any other drugs which the minister considers necessary to be re-examined , the period is 4 years.	4 or 6 years
Australia	Therapeutic Goods Act, 1989	While evaluating therapeutic goods for registration, protected information should not be used for evaluation.	5 years
China	Decree of State Council no.360 (Regulations for implementation of the Drug Administration Law of the People's Republic of China) Also ensures compliance with Article 39.3 of TRIPS Agreement.	Can only be disclosed in case of public need or when steps are taken to ensure that the data is protected against unfair commercial use.	6 years
Hong Kong	Pharmacy and Poisons Regulations, Ordinance Cap 138	Undisclosed documentation submitted by the manufacturer as support for registration is not referred to or relied upon. In case of generic products, if the innovative product has been registered for 5 or more than 5 years, clinical data is not required.	Not specified
Japan	Medical Devices, Article 14-4	8 years is the re-examination period assigned for medicinal products with active new ingredients.	8 years
Malaysia	Regulation 29 of the control of the drugs and cosmetics regulations 1984	The period of data-exclusivity is 5 years for a new product containing new ingredients and 3 years for a new variation of a registered product. Exceptions for data-exclusivity – Ensuring public health, national security, national emergency, non-commercial public use, and any emergency as declared by the government.	5 years
New Zealand	Medicines Act, 1981 no.118	Disclosing or using that confidential supporting information to determine whether to grant any application other than the application to which the information is related or when the minister is of the opinion that the disclosure or use is necessary to ensure public healthy and safety.	5 years

Ensuring Public Interest while granting Test-data Protection/Data-exclusivity

In recent times, the idea of securing undisclosed data having high economic worth has gained a lot of momentum to be protected as undisclosed data under the TRIPS. Generally, this information was ensured protection as competitive advantages under the common law.

Data-exclusivity is a transitional concept of protection of exclusive test data in the form of publicly undisclosed information which is in between the protection of the data in the form of trade secrets based on the principles of equity and good faith, and the domain of patent protection; which requires invention to be new, having an inventive step and capable of industrial application.[29]

Before introducing to the market, the originator of the new drug has to invest huge amount of time and money to demonstrate safety and efficacy of new chemical entity, before the regulatory authority to obtain license to market the product. This is achieved through various test trial or clinical trials. While the discovery and development of another particle takes around 8 to 10 years and costs millions of dollars, creating the test information takes about half of the time and cost. Hence, commercial value of this data becomes significant at the time of acquiring marketing approval from administrative authority. This right of exclusivity is essential for brand names to recoup their investment.

Data-exclusivity provides the originator with rights to preclude third parties from relying on the data to obtain marketing approval for a specific period of time.[30] However, it does not prevent third parties from generating their own data. Generic manufacturers can also apply for marketing approval provided that they conduct their own tests to prove the efficacy and safety of their product. For example, in the US and Taiwan, a new molecular entity (NME) is given five years of date exclusivity. However, after those five years are up, other companies can apply for market approval using the same data, and thereby avoid the costs associated with generating their own data. Therefore, such data-exclusivity doesn't ultimately prevent other companies from obtaining market approval, but it can slow them down a bit to incentivize the original holder.[31]

The main object of granting data-exclusivity to this originator's data is to incentivize new development in the market. As we have figured out that every such development requires huge R&D cost along with safety and efficacy trials cost, hence, the economic loss of such agent must be protected in terms of not allowing its competitors from using the same data for seeking approval for similar or bio equivalent drug by granting exclusive right to originator.

The idea is not to give monopoly market rights but only to let the original player to recover the at least the cost. Data-exclusivity is not an extension of patent rights, and it does not prevent the introduction of generic versions of the innovative drug during the data-exclusivity period, as long as the marketing approval of the generic version does not use or rely upon the innovator's test data.

By providing a means for the innovator to potentially recoup the costs involved in conducting any locally required clinical tests for marketing approval and the significant costs of introducing a new product to the market, countries which offer data-exclusivity are encouraging businesses to move their product, investment and potential manufacturing to their markets earlier.[32] If other companies could immediately use these data to obtain their own marketing authorization, thus competing with the innovator, there would be less incentive for the innovator to invest in that market or to conduct the necessary trials.

But in some sense it does create a monopoly for certain period and impedes the growth of Generic drugs in the market which has lower cost and more affordability particularly in developing and least developed countries. This is why data-exclusivity is controversial because it plays an important part in staving off competition from a generic version even if the patent is invalidated. In effect, data-exclusivity indirectly gives innovator drug companies a period of protection from competition.

The cost of medicine under the Data-exclusivity regime tends to be very high as the companies tend to not only recover the cost but also pile in as much profit as they can. They, sometime, mark up the price of their product by 200%-300% as in cases as Mylan's pricing of Epipen and Pfizer's profits from Lipitor.[33] Such situation deny the right of access to medicine to poorer sections of the world. Hence, the need arises to balance both the interest groups and harmonize incentivization and affordability. The economic imbalance and need for such safeguards on the developing countries has already been recognized in the Doha Declaration of 2001. Para 4 of the Doha Declaration states that:

"We agree that the TRIPS Agreement does not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all."[34]

The Doha Declaration thus provides the flexibility to the norms of WTO and India has by far creatively interpreted these terms and utilized the flexibilities. It is yet to legislate on terms of data protection and exclusivity while such matters are generally dealt with some subsidiary rules and common law principles. Though in recent times, there is tremendous pressure on India by developed countries like US and EU, to provide such laws in their territorial market but being one of the largest producer of generic drug in the world, it must be considerate to its domestic market as well as the economic viability of such approach on its general population. Therefore, the ideal approach should be to introduce a fair pricing system along with data-exclusivity regime so that public health does not get impaired in the tussle between incentives and affordability.

Indian Position

Protection of pharmaceutical regulatory data is a hotly debated issue in India and despite several attempts; Indian government could not adopt a clear policy on this issue. The conflicting interests of generic manufacturers and multinational pharmaceutical industry have largely shaped this debate in terms of national interest and public policy issue. India is increasingly facing pressure from the USA to implement a TRIPS-plus data-exclusivity regime. India has conventionally maintained that its existing regime based upon a combination of common law protection of trade secrets law[35] and the provisions of the Drugs and Cosmetics Act 1940 (India) is sufficient to fulfil the obligation of the 1994 TRIPS Agreement and a standalone legislative framework, especially the one identical to the US system, is not a suitable preposition. However, this position could not be sustained over the periods of time as proprietary data submitted to drug registration authority was virtually used by Indian generic manufacturers in every single case without proper authorization.

The underlying logic of data-exclusivity suggests that it is an expression of trade-secrets, and that as such, data-exclusivity should be independent of patents; hence, in the absence of any express legislation, data-exclusivity is claimed as other forms of intellectual property. Various laws in India are as following-

a) The Official Secrets Act, 1923

Section 5 of the Official Secrets Act provides that unauthorized disclosure of official secrets is a punishable offence. This provision is also applicable to government employees.

b) Drugs & Cosmetics Act, 1940

Rule 53 of the Drugs and Cosmetics Rules, 1945 provides that for restriction on the officer of disclosing any data received by him except in case of official business and court orders.

c) The Insecticides Act, 1968

Once the original registration is obtained by the originator/ first applicant u/s 9(3) of the Insecticides Act (1968), a large number of 'me too' registrations are obtained immediately, u/s 9(4) of the Act – virtually without any test data.

Realizing the inadequacies of its current system, the Indian government had constituted an inter-ministerial committee in February 2004 to recommend appropriate framework for the implementation of obligation of Article 39.3 of the 1994 TRIPS Agreement. This Committee took considerable time in its deliberations and finally submitted its report on 31 May 2007.[36] This Committee, which is commonly known as Satwant Reddy Committee, recommended separate protection regimes for agrochemical products, traditional medicines and pharmaceuticals. To protect undisclosed information submitted to drug regulatory authority, the Report recommends that:

"*There is an established system of marketing approval and evaluation of test data generated for drugs in India. While there is need to improve the system and make necessary legal changes and explicitly provide for the minimum requirements under Article 39.3 of TRIPS, any higher standards of data protection should be done after a careful study of its impact on the sector and public to avoid any adverse repercussions in the long run. India has adopted product patent regime with effect from 1 January 2005, the impact of which is yet to be seen. Therefore, a somewhat cautious approach may be in the interest of the country. Any misgivings in the public mind about the need or the justification for the new system need to be addressed over a period of*

time. A calibrated approach with a transitional period, therefore, appears to be best suited for India. During the transitional period, the minimum requirements under Article 39.3 of TRIPS can be implemented. Also, this period can be utilized to educate the public and industry so as to allay their apprehensions on the issue. The capacity and the physical infrastructure available with the Regulatory Authority would need to be suitably strengthened and upgraded."

The Report clearly rejects the option of adopting a TRIPS-plus data-exclusivity regime and instead proposed an alternative model with transition arrangements. The compromised reached in the Report has some negative implication too. Ideally, India should adopt a more enabling data protection regime, which can allow generic companies to use proprietary data subject to payment of royalties. A complete restriction on the use of data, though for a limited period of time, would inevitably affect the functioning of generic companies. There are apprehensions that such a system would gradually move to a fully fledged data-exclusivity regime. This Report contains several important recommendations which have as yet not been taken up by the government. The initial response of the Ministry of Health was not welcoming on certain aspects of Committee's recommendation but it is recently reported that Ministry has now requested to the World Health Organization to commission a 'study on the impact of Satwant Reddy Committee Recommendations on the Indian Pharmaceutical Industry.' [37,38]

Drug manufacturers dominate Indian pharmaceutical sector. Not only is the initial research and development behind the generation of the drug expensive, but also an additional cost is incurred during clinical trials to prove the efficacy of the drug. Presence of data-exclusivity provisions provides incentive to the drug manufacturers for further investments or new adaptations of the existing drug. Under the Indian Patent Act, patent qualification criteria are stringent. Modifications of existing drugs or improvements will not be eligible for patent protection.

As stated earlier, import, export, manufacturing and distribution of drugs in India is regulated by The Drugs and Cosmetics Act, 1940 and the Drugs and Cosmetics Rules,1945. According to Rule 122E of the Drugs and Cosmetics Rules, 1945 a new drug is recognized for a period of four years since the first approval from Indian Regulatory Authorities. The Central Drugs Standard Control Organization (CDSCO), the licensing authority, requires all new generic versions of the manufacture within the four years to be registered with it. Under the Indian legal regime, protection provided by the data-exclusivity provisions is completely different from the protection as provided under the patent regime. Even if a new drug is not patentable, it would still qualify for data-exclusivity provisions as a "new drug" under section 122E. Both protections are mutually exclusive for each other. After the end of customary four years, the subsequent manufacturers can seek permission from the central authority to rely on the existing data. The laws also require bioavailability and bioequivalence test results with existing drugs to be provided by generic manufacturers to secure regulatory approval. Such tests can be waivered in public interest. According to the laws in India, data with respect to the safety of a drug needs to be submitted in India, no matter the safety and efficacy has been established in another country. The Trade Secret protection is provided as a common law remedy. Other existing laws are The Official Secrets Act, 1923; The Insecticides Act, 1968 and the Indian Patents Act, 1970. These legislations are mostly preventive in nature.

Optimum Period for Test Data to be Reasonably Excluded for Generic Companies

To decide a particular time frame for granting access to the data to the generic companies one must look at the factors of the market and role of generic drugs in that market. As has been discussed earlier, the generic drugs provide affordability of innovative and necessary cure to large section of poor population. While the big companies tend to concentrate on their profit motive, the poor population is left in astray. These generic companies cater to these people in need by bringing down the cost of the pharmaceuticals and making them feasible. Therefore blocking the generic companies access to such data not only mars the prospects of the company but also hinders the access to medicine to those poor.

There are three reasons why generics have become a part of the global pharmaceutical industry. First, generics play an important role in the global pharmaceuticals industry. They do not just cater to the health needs of the poorer countries but also to kick-start innovation in these nations. Second, historically, copying has been the first step for innovation even in

the developed world. Thus for innovation in pharmaceuticals to proliferate all over the world, generics will serve as the first step to kick-start the industry. Especially for least-developed countries, the leap to innovation in pharmaceuticals in the future will occur only when they take the first step of being able to establish generic drug manufacturing facilities locally. Third, even in developed nations that are obsessed with patents, like the United States, the astronomical cost of medication has resulted in an increased appreciation for the role of generics. Thus generics are viewed as important components to enable market competition as well as to challenge bad patents. In all, the generic drug industry represents an important industry catering to the healthcare needs of a large segment of the global population. [39]

The time frame in the data-exclusivity regime must be decided upon above mentioned factors. Not only the incentivization and cost recovery of the data originator is to be considered, but also the importance and utility of the generic drugs in the market should be the factor while making a decision. Longer period of blockage to the test data will create more monopoly and lesser accessibility.

Conclusion

The issue of data-exclusivity is quite debatable as several issues are attached to it. These issues are concerned with availability of generic medicines especially in developing countries particularly those having high population of patients with HIV/AIDS. The debate revolves around the interpretation of Article 39.3 of TRIPS Agreement and whether the said article obliges for data-exclusivity or not.

Countries which have a strong research based pharmaceutical industry believe in incentivizing the industry through protection in the form of data-exclusivity. All WTO members, since January 1, 2000[40] have been mandated to have provisions, which are TRIPS Compliant, and to enforce this provision in the most efficacious manner possible. The only exception to this mandate is the least developed countries. It is acknowledged that these countries do aim to provide such protection as required under TRIPS, but are unable to keep up with the provisions.

India does not have any act which corresponds to the Hatch-Waxman Act and no legal provision which complies with Article 39(3)[41] of the TRIPS agreement. The Officers Secret Act, 1923 binds public officers from disclosing any confidential information in a manner, which is not authorized. Otherwise, there is no statutory provision, which protects the data submitted to regulatory authorities for testing. Developed countries like U.S and EU try to enforce the provisions of data-exclusivity in the form of Free Trade Agreements (FTA's) with developing countries. As a result, most developing countries have opted for data-exclusivity *via* FTA's. We must question why this TRIPS-plus measure has been so widely adopted notwithstanding it harms access to medicines in developing countries. The reason is that it is forced upon them and they are threatened by developed countries due to the possibility of trade sanctions.

Moreover, these developed countries are also seeking amendments in Indian law to introduce data-exclusivity. As we have already discussed there are various reasons why data-exclusivity laws should not be brought into India at this stage. An analysis of Article 39.3 of TRIPS shows that TRIPS speaks of data protection in a flexible manner and does not talk about data-exclusivity. Thus, the argument that data-exclusivity must be provided in India to be in compliance with TRIPS is fallacious.

The pharmaceutical MNC's demand for data-exclusivity is clearly a TRIPS-plus demand and against the object and principles of the TRIPS Agreement. It violates the flexibilities inherent in the TRIPS Agreement and also against the Paragraph IV of Doha Declaration on Public Health, which clearly says the TRIPS Agreement can and should be interpreted and implemented in a manner supportive of the WTO members, right to protect public health and, in particular, to promote access to medicines for all.

Developing countries say that the data-exclusivity poses a fundamental concern for access and affordability. For example, in case of medicines where the generic drug entry will be stopped as are result of the monopolization of the clinical trial test data. India is not implementing the data-exclusivity in pharmaceutical sectors mainly to protect the public health because India is considered as one of the largest populated country, where 60% of the people are suffering from some diseases and the medicines are not easily affordable by them. The per capita income of the people of India is very low; therefore, there is need for the market of generic drugs. The data-exclusivity delays the entry of generic drugs in

the market and that is main reason of the Indian government for not providing data-exclusivity to the same. So, the decision of India of not allowing data-exclusivity is not only TRIPS compliant but also in nation's interest. It must be appreciated that we need not to follow precedents set by developed countries that are primarily based on a different societal set up and is guided by commercial exigencies. The larger interest of India requires us to stick to the obligations of TRIPS Agreement and not to venture into the arena of TRIPS-plus terrains. The TRIPS Agreement nowhere stipulates and obligates India to confer data-exclusivity and the only requirement is to prevent an unfair commercial use of the data submitted.

There is no doubt that expensive and extensive research is done to develop a new drug molecule but if it is not available to poor in the developing countries and least developed countries what would be the use of such research in society. There is a product patent in India and MNC's can recoup the expenses involved in the research process during the term of patent. Demand for the protection of research data in the form of data-exclusivity does not appear to be genuine.

Currently, India does not acknowledge any data-exclusivity arrangements. It has adopted most flexible interpretation of Article 39.3 of TRIPS Agreement. The interpretation of Article 39.3 needs to be given with the help of maxim "*expressio unis est exclusion alterius*" which says "what is not explicitly included is thereby excluded". It is said that data-exclusivity arrangements, whenever added to the Indian Drugs and Cosmetic Act, will prevent India's drug regulatory agency from referencing or otherwise relying on registration data previously innovator drug companies in order to gain regulatory approval for the rapeutically equivalent generic versions.[42]

Satwant Reddy Committee, which was formed by the Government of India to look into the matter, has made certain recommendations and safeguards in its report submitted in 2007. The report is yet to be implemented by the government. The Committee clearly recommended that the obligations under TRIPS Article 39 can be met merely by non-disclosure of the data submitted for marketing approval to the regulatory authority and also mentioned that non-disclosure did not necessarily preclude the reliance on that data by regulatory authority for approval of the same product by any subsequent applicant.[37]We think that before arriving at any decision, Government of India must consider the socio-economic conditions of India. It must take adequate caution in its current negotiations towards formation of FTA with European Union and USA in particular. Protection of public interest must be given preference as compared to the interest of MNC's. Instead of introducing data-exclusivity, suitable legislative measures should be taken for the protection of data against unfair use, and this would ultimately resolve the ground on which MNC's are advocating data-exclusivity. Therefore, until the Indian government reaches a stage at which data-exclusivity laws will be useful to the Indian Pharmaceutical sector, the move to amend the DCA and other laws to accommodate data-exclusivity should therefore be opposed.

Balancing the Interests: Possible Solutions

Compensatory Liability Approach

This is also known as the middle road or the cost sharing option. Under this approach the generic companies who want to enter the market can rely upon the originator's data if they compensate their investments in generating this data.[43] This compensatory liability approach is already in effect in the US for protecting agricultural test data. Under this approach the data can be automatically used from the time of its submission, following payment of a reasonable compensation by the generic company wishing to enter the market. Further, bioequivalence can be used any time without limitations due to exclusivity periods. This approach is the fairest option for tackling the free rider problem. The generic company can enter the market immediately after patent expiration conditioned upon having proved bioequivalence.

Automatic Waiver in Cases of Compulsory Licensing

It is said that waiving data-exclusivity in cases of compulsory licensing would be favorable for addressing public health concerns. As explained, some FTA's have laid down safeguard provisions pursuant to the Doha Declaration.[44] However, these provisions were drafted broadly and did not specify a waving of data-exclusivity.

Adopting the early working exception.[45] Under this patent exception, founded on Article 30 TRIPS, generic pharmaceutical companies may initiate application procedure for obtaining marketing approval during the patent term. As it is aimed to comply with the requirements of the regulatory

approval there is no commercial use of the patented invention.

Adopting this exception would benefit generic pharmaceutical companies in developing countries as long as they would have started at an early stage their application procedure for obtaining marketing approval. Therefore, they would market their drugs immediately after the patent term expires because their market entry would not be delayed due to the lengthy process of marketing approval.

Termination of Data-Exclusivity upon Patent Expiration[46]

It has been argued that patent term extension due to data-exclusivity harms developing countries interests. Particularly, it delays generics entry. Therefore, to avoid patent extensions it should be considered a clause either for domestic law or FTA's prohibiting any extra data-exclusivity period beyond the 20 year of patent protection.

In a hypothetical case, if a pharmaceutical product enters into the market in the 16th year of patent's life, having been granted the market authorization, the protection left under patent law would be for 4 more years. Nevertheless, due to data-exclusivity it could be extended 1 more year according to the 5 year rule in USA, or even longer pursuant to the 10 years rule in EU.[47]

In majority of cases data-exclusivity runs simultaneous with patent term. In consequence the implementation of this alternative will only be relevant for those cases in which data-exclusivity runs independently. Furthermore, it does not affect pioneers companies interests as they still have an exclusivity period for recouping their R&D investments in generating the data.

Limiting the Term of Protection

Reducing the 5-year term of data protection could be less restrictive measure. In this the pioneer companies would argue that they are unable to recoup their investments during shorter periods. To this end, economic analysis would be required to establish the adequate term of protection in which both interests might be satisfied.[43] Moreover, pharmaceutical companies must justify their R&D and innovation expenses in generating the data. Then, only in those cases where the amount of money is not compensated through patent protection, data-exclusivity protection might extend to 5 years, otherwise not.

Limiting the Scope

One possible limitation that might be considered as fair balancing of interests would be to establish data-exclusivity only for pharmaceutical products that do not meet the criteria for patentability. As these would not benefit from a 20-year development recoupment period, data-exclusivity is justifiable as it would be their only means of protection.

Implementing these alternatives developing countries would require a case by case analysis taking into account the cost and benefit of these opportunities. Among these alternatives the compensatory liability approach, seems the most appropriate alternative to balance pioneer and generic companies interests as it tackles the free rider problem and devoid further delays of generics market entry. And as FTA's are spreading throughout the world, among developing countries, there is a clear opportunity for contemplating and agreeing upon alternatives means of Pharmaceutical test data protection.

Standing as we are almost two decades since the seminal Doha Declaration on the TRIPS Agreement and Public Health,[1] which in itself, had been no less than a paradigm shift, ushering in a climate and indeed, an era hallmarked by significantly greater focus on issues related to intellectual property and public health, - we do need to take sober stock of certain facts.

While considerable strides have been made and milestones achieved to help us, the global community, better recognise public health values whilst framing the intellectual property models within existing international trading systems (the works of the WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property and the WIPO Development Agenda, to name a few), - nevertheless, major challenges continue to persist, of which, a prominent few happen to be: (i) overcoming key infectious diseases, (ii) increasing research for neglected diseases, (iii) combating the growing burden of non-communicable diseases, as well as (iv) other emerging public health threats and a changing economic climate, - the core complaints within each of which, can, either directly or otherwise, be traced right back to the "access-imbalance" issue, - highlighting with acute urgency, the complex and inextricable relationship between public health, innovation and trade, which demands a far more holistic approach in the future (involving a wide range of actors) than exists at the moment.

It is self-evident, that due to these gaps in the ongoing discussions, the need for a more flexible, inclusive and holistic perspective addressing these practical realities has been increasingly felt. Policymakers, legislators and stakeholders, all need to be keenly aware of the potential pitfalls of proposals that may seem attractive on paper the National IPR Policy (circa 2016),[48] (ii) the National Health Policy (circa 2017)[49] and most recently, (iii) the Delhi Declaration (circa 2018),[50] - but need to be carefully scrutinised, tested out and meticulously calibrated, so as to be rendered optimally flexible in practice.

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